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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/570,836	12/13/2006	Bradley John Walsh	36180-102911	5258

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EXAMINER	
COOK, LISA V	
ART UNIT	PAPER NUMBER
1641	
MAIL DATE	DELIVERY MODE
08/23/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/570,836	WALSH ET AL.	
	Examiner	Art Unit	
	Lisa V. Cook	1641	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *13 December 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-15* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-15* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *12/13/06*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claim Status

1. Currently claims 1-15 are pending and under consideration.

Information Disclosure Statement

2. The listing of references in the specification is not a proper information disclosure statement. 37 CFR 1.98(b) requires a list of all patents, publications, or other information submitted for consideration by the Office, and MPEP § 609 A(1) states, "the list may not be incorporated into the specification but must be submitted in a separate paper." Therefore, unless the examiner on form PTO-892 or applicant on form PTO-1449 lists the references, they have not been considered.

3. The information disclosure statement filed 13 December 2006 has been considered as to the merits before First Action.

Drawings

4. No drawings were filed in the instant application.

Specification

5. The use of the trademarks has been noted in this application. For example see, TEXAS RED on page 7 line 27 and SILICA on page 12 line 19. They should be capitalized wherever it appears and be accompanied by the generic terminology.

Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner, which might adversely affect their validity as trademarks.

Abstract

6. This application does not contain an abstract of the disclosure as required by 37 CFR 1.72(b). An abstract on a separate sheet is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

7. Claims 2-4 and 14-15 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

A. Claim 2 is vague and indefinite because it is not clear if the claim is directed to a peptide marker *comprising* the recited sequences or a peptide marker *consisting of* the recited sequences. Although the claim reads on "a peptide marker selected from the group consisting of", this is Markush language indicative the group. However, this does not address the sequences themselves (are they open or close). It is suggested that the appropriate transitional phrase be added to the claim to eradicate ambiguity. Appropriate correction is required.

B. Claim 3 is vague and indefinite in utilizing the phrase "blood products". Because the term is not defined in the disclosure, the metes and bounds cannot be determined. Is it applicants' intent to claim any material containing blood, any product useful in blood analyses, or any product derived from blood? Please clarify. It is suggested that the term be eliminated in order to obviate the rejection.

C. Claims 14 and 15 are vague and in definite because it is not clear as to what is meant by the phrase "having an amino acid sequence". It is suggested that the claim recites "comprising" or "consisting of" in order to obviate this rejections. Please clarify the claim.

Claim Rejections - 35 USC § 102

8. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

I. Claims 9-13 are rejected under 35 U.S.C. 102(b) as being anticipated by Srivastava et al. (WO 01/92474 A1).

Srivastava et al. disclose human alpha 2 macroglobulin (α2M) fragments. See page 4 lines 1-10. Sequence identification number 5 comprises the instantly claimed SEQ ID NO:2 (see sequence search Result 18, figure 13B, and Srivastava et al. page 15 line 35 through page 16 line 6). The peptides can be purified by conventional procedures. See page 24 lines 30-33.

Srivastava et al. also disclose labeled monoclonal or polyclonal antibodies that specifically recognize disclose human alpha 2 macroglobulin (α2M). See page 25 section 5.1.3 and page 50 lines 27-30, for example. The peptides are taught to be useful in diabetes. See page 69 section 5.7

II. Claims 1, 3, and 8 are rejected under 35 U.S.C. 102(b) as being anticipated by James et al. (Journal of Clinical Pathology, 1980, Vol33, pages 163-166).

James et al. disclose the measurement of serum α_2-macroglobulin levels in diabetes. The α_2-macroglobulin levels in diabetic patients were found to be significantly higher than in age and sex-matched controls. See abstract. A urine sample was obtained from all the patients at every clinic attendance and tested for protein. See page 163 2nd column - last paragraph. Serum α_2-macroglobulin levels (expressed as mg per dl) were measured by a standard Mancini gel diffusion method. See page 164 1st column. The results indicated that the determination of α_2-macroglobulin levels in diabetic patients may provide useful additional information with respect to both the ease with which control of blood sugar levels can be achieved and the propensity to develop retinal complications. See page 166 1st column.

Claim Rejections - 35 USC § 103

9. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102((e), f) or (g) prior art under 35 U.S.C. 103(a).

III. Claim 2 is rejected under 35 U.S.C. 103(b) as being unpatentable over James et al. (Journal of Clinical Pathology, 1980, Vol33, pages 163-166) in view of Srivastava et al. (WO 01/92474 A1).

Please see James et al. (Journal of Clinical Pathology, 1980, Vol33, pages 163-166) as set forth above.

James et al. differs from the instant invention in not specifically teaching peptide makers comprising SEQ ID NO:2.

However, Srivastava et al. disclose human alpha 2 macroglobulin (α2M) fragments. See page 4 lines 1-10. Sequence identification number 5 comprises the instantly claimed SEQ ID NO:2 (see sequence search Result 18, figure 13B, and Srivastava et al. page 15 line 35 through page 16 line 6). The peptides can be purified by conventional procedures. See page 24 lines 30-33.

Srivastava et al. also disclose labeled monoclonal or polyclonal antibodies that specifically recognize disclose human alpha 2 macroglobulin (α2M). See page 25 section 5.1.3 and page 50 lines 27-30, for example. The peptides are taught to be useful in diabetes. See page 69 section 5.7

Therefore, it would have been obvious at the time the invention was made to a person having ordinary skill in the art to employ human alpha 2 macroglobulin (α2M) fragments comprising SEQ ID NO:2 as taught by Srivastava et al. in the diabetes detection procedure of James et al. because Srivastava et al. taught that the peptides are taught to be useful in diagnosis, prognosis, and treatment of diabetes. See page 69 section 5.7 and page 24 section 5.1.2.

IV. Claims 4-7 are rejected under 35 U.S.C. 103(b) as being unpatentable over James et al. (Journal of Clinical Pathology, 1980, Vol33, pages 163-166) in view of Kumar et al. (Current Science, Vol.82, No.6, 25 March 2002, pages 655-663).

Please see James et al. (Journal of Clinical Pathology, 1980, Vol33, pages 163-166) as set forth above.

James et al. differ from the instant invention in not specifically teaching urinary analysis of proteins by two dimensional electrophoresis and mass spectrometry (MALDI-TOF).

However, Kumar et al. teaches that the proteomes of urinary samples from patients with different renal conditions can be evaluated by two-dimensional electrophoresis and MALDI-TOF to identify relevant peptides. See abstract. On condition considered was kidney failure (which can be a cause of diabetes). See attached Mosby Medical encyclopedia page 244, © 1996. The proteins identified included albumin, alpha-1-antitrypsin, alpha-1-acid glycoprotein 2, Zn-alpha-2-glycoprotein, and alpha-1-microglobulin. See page 661, Discussion. The paper teaches that this type of protein measurement may make it possible to identify and use protein markers to define and categorize renal pathology. See page 663, 2nd column.

One of ordinary skill in the art would have been motivated to do this in order to rapidly and accurately identify protein markers in an effort towards developing specific urinary protein database for specific renal conditions. See Kumar et al. page 656, 2nd column.

V. Claims 14-15 are rejected under 35 U.S.C. 103(b) as being unpatentable over James et al. (Journal of Clinical Pathology, 1980, Vol33, pages 163-166) in view of Kumar et al. (Current Science, Vol.82, No.6, 25 March 2002, pages 655-663) and further in view of Srivastava et al. (WO 01/92474 A1).

Please see James et al. (Journal of Clinical Pathology, 1980, Vol33, pages 163-166) in view of Kumar et al. (Current Science, Vol.82, No.6, 25 March 2002, pages 655-663) as set forth above.

James et al. in view of Kumar et al. differs from the instant invention in not specifically teaching peptide makers comprising SEQ ID NO:2.

However, Srivastava et al. disclose human alpha 2 macroglobulin (α2M) fragments. See page 4 lines 1-10. Sequence identification number 5 comprises the instantly claimed SEQ ID NO:2 (see sequence search Result 18, figure 13B, and Srivastava et al. page 15 line 35 through page 16 line 6). The peptides can be purified by conventional procedures. See page 24 lines 30-33.

Srivastava et al. also disclose labeled monoclonal or polyclonal antibodies that specifically recognize disclose human alpha 2 macroglobulin (α2M). See page 25 section 5.1.3 and page 50 lines 27-30, for example. The peptides are taught to be useful in diabetes. See page 69 section 5.7

Therefore, it would have been obvious at the time the invention was made to a person having ordinary skill in the art to employ human alpha 2 macroglobulin (α2M) fragments comprising SEQ ID NO:2 as taught by Srivastava et al. in the protein detection procedures of James et al. in view of Kumar et al. because Srivastava et al. taught that the peptides are taught to be useful in diagnosis, prognosis, and treatment of diabetes. See page 69 section 5.7 and page 24 section 5.1.2.

10. For reasons aforementioned and already of record, no claims are allowed.

Remarks

11. Prior art made of record and not relied upon is considered pertinent to the applicant's disclosure:

A. Parker et al. (WO 02/090929 A2) disclose methods employing electrophoresis and mass spectrometry to measure proteins.

B. Larsen et al. (WO 02/097441 A2) teach the measurement of novel proteins associated with diabetes via electrophoresis and mass spectrometry analysis.

12. Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform to the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The Group 1641 – Central Fax number is (571) 273-8300, which is able to receive transmissions 24 hours/day, 7 days/week. In the event Applicant would like to fax an unofficial communication, the Examiner should be contacted for the appropriate Right Fax number.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lisa V. Cook whose telephone number is (571) 272-0816. The examiner can normally be reached on Monday - Friday from 8:30 AM - 4:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le, can be reached on (571) 272-0823.

Any inquiry of a general nature or relating to the status of this application should be directed to Group TC 1600 whose telephone number is (571) 272-1600.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR.

Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see httpr//pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

LONG V. LE 8/20/07
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600

Lisa V. Cook
Patent Examiner
Art Unit:1641
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571-272-0816
8/14/07